

Access strategies by the pharmaceutical industry

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5 billion people
have access to medicine
2 billion to go

Acknowledgment: **access to
medicine
FOUNDATION**

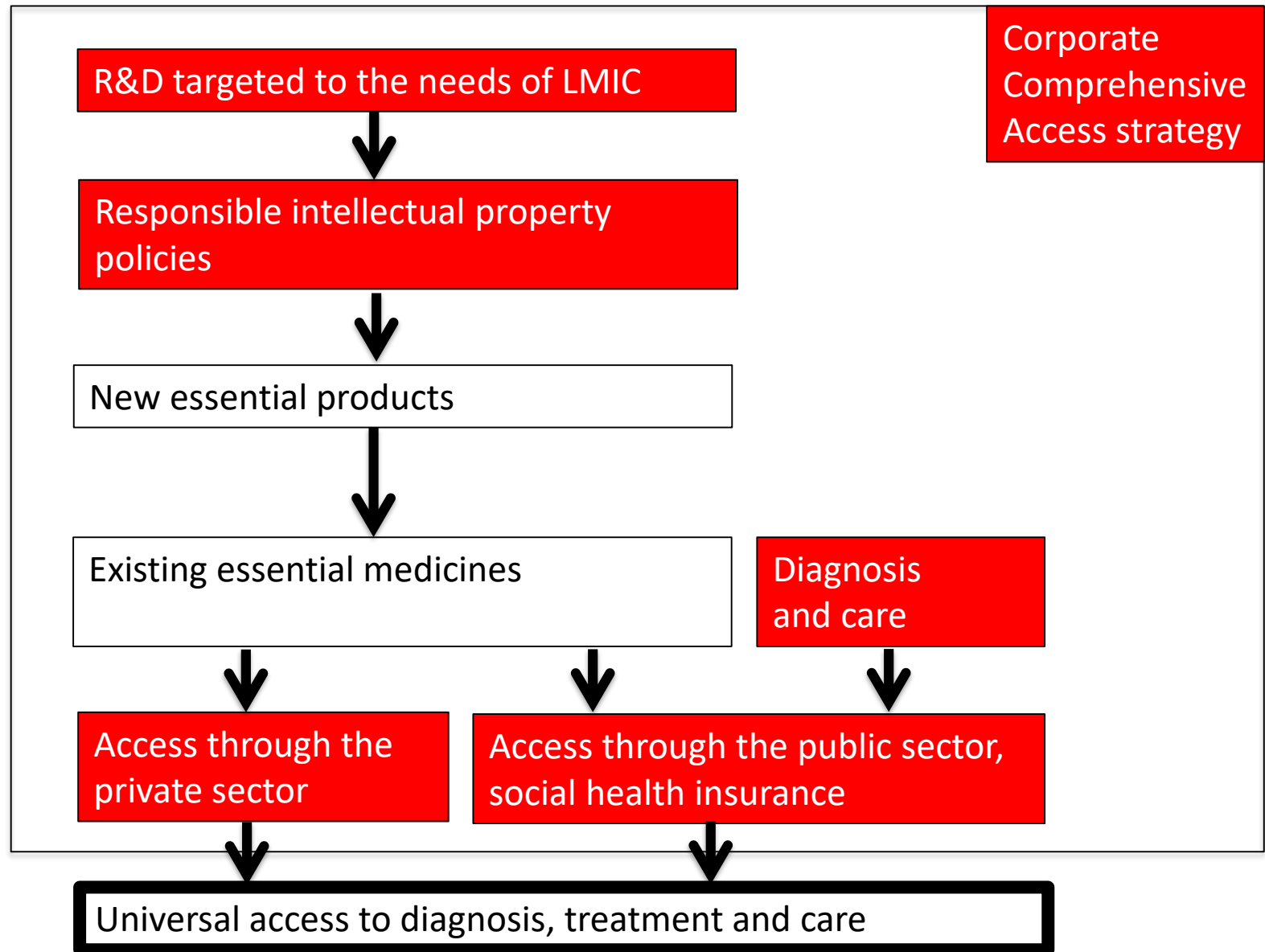
Introduction

- 83% of people live in Low and Middle Income Countries
- 2 billion people lack access to essential medicines



- 5 years after the introduction of even the most innovative medicine, only 10% of people in high-income countries have access, and <1% in emerging markets

Industry contributions to improving access in LMIC



Objective: R&D targeted to the needs of LMIC

- Targeted research, following WHO / GAP priorities
- Company R&D expenditure publicly disclosed
- R&D capacity building in LMIC, including clinical trial capacity

Objective: Responsible intellectual property policies

- Public disclosure of patent status of products
- Non-enforcement of patents in LMIC, patent wavers
- Responsible licensing, e.g. through Medicine Patent Pool
- No ever-greening of patents
- Public position on Doha Declaration on TRIPS



Outcome: New essential products for LMIC



Objective: Affordable cost-effective products available



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graph TD; A[Objective: Affordable cost-effective products available] --> B[Objective: Improved access through the private sector]; A --> C[Objective: Improved access through the public sector and social health insurance]; A --> D[Good quality diagnosis and care];
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Objective: Affordable cost-effective products available

- Wide registration of essential products
- Rapid reporting of substandard or falsified products

Objective: Improved access through the private sector

- Intra-country differential pricing
- Responsible sales and business practices

Objective: Improved access through the public sector and social health insurance

- WHO Prequalification of products
- Transparent prices for public sector
- International or pooled procurement
- Sustainable donation programmes
- Capacity building in manufacturing

Good quality diagnosis and care

- Capacity building in diagnosis and patient education

Examples of “Best Practice”

Access Planning



Dolutegravir Paediatric

- WHO prequalification
- Registration commitments
- 15 non-exclusive royalty-free voluntary licenses
- Partnerships with UNITAID, CHAI and two generic manufacturers
- Guaranteed supply at manuf.cost until generics are available

Access Strategy



Novartis Access Programme

- 15 products targeting 4 NCDs
- Tiered pricing along full income pyramid, also private sector
- Local partnerships, social business models
- Capacity building

Recommendation to WHO:

Develop guidance for pharmaceutical industry

- **Good guidance for government access policies exists:**
 - WHO Guidelines for National Medicine Policies (2001)
 - Lancet Commission on Essential Medicines Policies (2017)
- **WHO guidance for pharmaceutical industry is needed:**
 - 31 WHO asks from the insulin industry (2021)
 - New WHO guidance needed: What should national governments demand from the pharmaceutical industry in support of access planning?